REMARKS/ARGUMENTS

By the foregoing amendment, independent claim 45 has been amended to clarify the claimed invention and to correct a typographical error. No new matter has been added.

As amended, claim 45 recites a method for repairing a hip joint by *hemiarthroplasty*. Also, as amended, step B of claim 45 specifies that at least body weight is used to determine the contact area of the hip joint required to ensure a hydrostatic pressure within a claimed range. This has support from originally filed claim 31.

Claims 45-54 have been rejected under 35 USC 103(a) as being unpatentable over Ries 5,782,928 in view of McGuire 2005/0202371 further in view of Zaleski 2003/0101076. Applicant respectfully disagrees.

Ries teaches a method for repairing a subject's hip joint by total hip replacement, rather than by *hemiarthroplasty* as recited by claim 45 as amended. It is well-known that in hip replacement surgery, either a total hip replacement can be performed or a hemiarthroplasty can be performed. In a total hip replacement, both the ball and socket parts of the hip joint are replaced – i.e. the patient's femoral head is replaced with a prosthetic femoral head and a prosthetic acetabulum is implanted in the patient's acetabular socket (see page 1, lines 12-18 of the description of the present application). After the prosthetic femoral head and a prosthetic acetabulum have been implanted, the prosthetic femoral head bears against the prosthetic acetabulum during articulation of the joint. In contrast, in a hemiarthroplasty, only the femoral head is replaced, with the acetabulum being left substantially untouched with the natural cartilage still in place (see page 1, lines 18-23).

Ries relates to the design of acetabular cup prostheses 10 for use in *total hip replacement* procedures. Ries does not provide any teaching relating to the design of prostheses for hemiarthroplasties, wherein no prosthetic acetabulum is implanted.

Of course, since Ries relates to a kit for total hip replacement wherein an acetabular cup is implanted, a space will not exist between the prosthetic femoral head of Ries and the inner surface of the reamed acetabulum in which fluid can accumulate, as required by claim 45. After the prosthetic system disclosed in Ries has been implanted, the prosthetic femoral head will bear

directly against the prosthetic acetabular cup, rather than the patient's reamed acetabular socket. Using the system of Ries, fluid may accumulate between the prosthetic acetabular cup and the patient's acetabular socket. However, this is in contrast to the invention of claim 45, wherein the prosthetic femoral head bears against the inner surface of the patients own reamed acetabular socket, and fluid accumulates in the space between the prosthetic femoral head and the *reamed acetabular socket.*

Ries discloses that a plurality of cup bodies can be provided in a range of sizes, each cup body having a companion reamer that enables the surgeon to ream the patient's acetabular socket, wherein the diameter of the cup body is about 9-12% greater than the diameter of the reamed socket. This allows the cup body to form a tight interference fit in the reamed socket once implanted (see col 12, lines 1-18 and col 6, lines 19-21).

There is no disclosure in Ries that the acetabular cup size or femoral head size is selected based on the weight of the patient. Typically, in a total hip replacement, the size of acetabular cup and femoral head are selected based on the size of the patient's natural acetabular socket. Typically an acetabular cup will be selected wherein the diameter of the concave recess of the cup matches the diameter of the patient's natural acetabular socket and the femoral head size is selected to match the size of the patient's natural femoral head that is being replaced. There is absolutely no teaching or suggestion in Ries to select the radius of curvature of prosthetic femoral head for a hip replacement based on the patient's weight. Ries only teaches that the diameter of the acetabular cup and reamer should be chosen such that the prosthetic acetabular cup is larger in diameter than the reamed acetabular socket, such that there is a tight interference fit of the prosthetic acetabular cup in the reamed socket.

Like Ries, McGuire relates to the design of acetabular cup prostheses 10 for use in total hip replacement procedures. McGuire does not provide any teaching relating to the design of prostheses for hemiarthroplasties, wherein no prosthetic acetabulum is implanted, and therefore McGuire is not relevant to the method of repairing a joint by hemiarthroplasty of claim 45.

Although McGuire teaches that cells subjected to compression develop into cartilage, there is no disclosure or teaching in McGuire of a method of performing a *hemiarthroplasty* wherein the patient's acetabulum is reamed and a prosthetic femoral head is implanted to bear

directly against the reamed acetabular socket, wherein the radius of curvature of the femoral head is selected using the patient's body weight, such that hydrostatic pressure in the range 0.01-5 MPa will accumulate in the space between the prosthetic femoral head and the reamed acetabular socket.

In contrast, in McGuire it is taught that it is desirable for the prosthetic acetabular cup to be adapted to control the stress and strain distribution at the bone-cup interface and within the surrounding bone, to activate bone growth and bone remodelling in the regions of the substance of the bone of the acetabulum, enhancing anchoring and adhesion of the prosthetic acetabular cup to the bone (see paras 100, 201 and 253 for example).

For example, in the embodiment shown in figure 1, the prosthetic acetabular cup 1100 has a concave outer surface that engages the patient's reamed acetabular socket when implanted, the concave outer surface having channels 1114 having an undercut configuration. After implantation, new bone cells will be induced to grow and gradually, over time, these migrate into channels 1114, creating an undercut locking engagement with the prosthetic socket 1100 (see paras 99 and 100).

McGuire teaches reaming of the acetabular socket and implantation of a prosthetic acetabular cup configured to stimulate growth of new bone that enhances anchoring and adhesion of the acetabular cup to the patient's acetabular socket. The aim of the system disclosed in McGuire is to anchor and adhere the prosthetic acetabular cup stably and non-movably to the patient's acetabular socket.

This is in contrast to the method of repairing a hip joint by hemiarthroplasty as recited by claim 45, wherein it is desired to stimulate the formation of new cartilage between the prosthetic femoral head and the inner surface of the reamed acetabular socket, in order to form a natural active bearing surface for the prosthetic femoral head to *articulate* against.

A person of ordinary skill in the art would not look to McGuire to provide any teaching on methods of repairing hip joints by hemiarthroplasty, since McGuire relates to total hip replacements. Even if a skilled person were to look to McGuire, the person would learn that compression exerted on the reamed acetabulum would stimulate growth of new bone cells, which can be used to enhance anchoring and adhesion of an implanted prosthesis

to the reamed acetabulum. In a hemiarthroplasty it is required that the prosthetic femoral head be able to articulate with respect to the patient's acetabular socket, and it is not desired for the prosthetic femoral head to adhere to the patient's acetabular socket. Therefore, a skilled person would not use any of the teaching from McGuire when trying to carry out a hemiarthroplasty, as the skilled person would not want the prosthetic femoral head to adhere to the patient's reamed acetabulum. Since McGuire teaches anchoring and adhesion of an implanted prosthesis to the reamed acetabulum, it teaches away from the present invention in which new cartilage is formed on the surface of the reamed acetabular socket against which the prosthetic femoral head will be able to articulate. For these reasons Applicants submit that Claim 45 is not anticipated by, nor rendered obvious by, the disclosure of McGuire.

The Examiner asserts that it would be obvious to measure a patient's body weight and use that information to inform the choice of prosthetic device. The Examiner cites Zaleski in this regard. Applicant respectfully disagrees.

Zaleski discloses a system for supporting clinical decision making having a repository for storing data and means for analysing data and identifying a pattern. Once such item of data that may be stored is the patient's weight. However, Zaleski does not include any teaching regarding selection of the size of a *prosthetic implant* based on a patient's weight. Furthermore, none of the other prior art of record teaches selecting the size of a femoral head for a hemiarthroplasty based on a patient's weight.

In prior art hemiarthroplasty methods, the femoral head is replaced as in a total hip replacement, but the acetabulum is left untouched with the natural cartilage still in place (see page 1, lines 20-23 of the description). There is therefore no step of reaming the acetabulum in a conventional prior art hemiarthroplasty. Unlike hemiarthroplasty methods of the prior art, the method of claim 45 provides a prosthetic femoral head and a reamer which are adapted to provide a restricted range of hydrostatic pressure in the joint to stimulate cartilage formation. The hydrostatic pressure of the joint is determined by the reactive force to the weight of the patient acting up through the joint as divided by the contact area across the joint through which the force is transmitted. In the claimed invention, the prosthetic femoral head has its radius of curvature (the radius of curvature being the radius of the partial sphere of the femoral head) selected to ensure that the contact area balances the reactive forces to the

weight of the patient, to give the required pressure across the joint. For example, for a relatively heavy patient who has a relatively small natural contact area of joint leading to a normal hydrostatic pressure outside of the range, the selected prosthetic femoral head will have a radius of curvature that is larger than the patient's natural femoral head curvature in order to increase the contact area and thereby reduce the pressure to within the desired range.

The Applicants have discovered that by determining the radius of curvature of the prosthetic femoral head and the corresponding reamer with reference to the patient's weight, the hydrostatic pressure in the liquid between the femoral head and the reamed socket can be subjected to a restricted range of pressure, which stimulates the formation of new cartilage between the socket and femoral head, but which does not risk adhesion of the prosthetic femoral head to the reamed socket as might be expected from the teaching of McGuire.

There is no teaching in any of the prior art to control the radius of curvature of the prosthetic femoral head for use in a hemiarthroplasty with reference to the patient's weight, therefore Claim 45 is novel and inventive in light of the prior art. Claims 46 to 54 are novel and inventive by virtue of dependency on claim 45.

Conclusion

The invention of claims 45 to 54 is not obvious in light of Ries in view of McGuire, as both disclose methods for repairing a hip by total hip replacement, whereas the present invention relates to hemiarthroplasty. A skilled person would not turn to prior art relating to total hip replacements, which use prosthetic acetabular cups, for teaching on how to try provide a better refined joint via a hemiarthroplasty procedure where no prosthetic acetabular cups are implanted. Furthermore, there is no teaching in any of the prior art, including Zaleski, to control the radius of curvature of the prosthetic femoral head in a hemiarthroplasty with reference to the patient's weight to provide a restricted range of hydrostatic pressure in the joint that stimulates cartilage formation. Claims 45 to 54 are therefore novel and inventive in light of the prior art.

Applicant hereby petitions for a two (2) month extension pursuant to 37 C.F.R. 1.136 and the Commissioner is authorized to deduct the fee for such three month extension as well

as any other fee properly deemed to be due in connection with the filing of this response from Deposit Account No. 50-0878.

Applicants' undersigned counsel hereby requests a telephone interview with the Examiner to discuss the foregoing and to facilitate prompt allowance of this application.

January 19, 2010

Respectfully submitted,

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